

### REMARKS

#### Status of Claims:

Claims 31-53 were pending in the application. Two claims were numbered "53." Claims 53-55 were renumbered as 54-56. Claims 31-56 are now pending. Each of the pending claims defines an invention that is novel and unobvious over the cited art. Favorable consideration of this case is respectfully requested.

#### Rejections Under 35 U.S.C. § 112, 1<sup>st</sup> Paragraph:

Claims 31-55 were rejected under 35 U.S.C. § 112, 1<sup>st</sup> Paragraph, as containing subject matter which was not described in the specifications in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Claim 31 is hereby amended to delete the recitation "phosphoglyceride." The relevant subject matter is not disclaimed. Claims 32-42 further specify the lipid. Original claim 8 specified the lipid as a mixture of phospholipids. Original claim 10 specified the lipid as phosphatidyl choline.

NO  
Claim 53 (renumbered as 54) was objected to as reciting "said tissue-promoting factor is a fragment thereof wherein said fragment retains biological activity." Support for this recitation may be found in original disclosure at page 15, lines 14-17.

#### Rejections Under 35 U.S.C. § 112, 2<sup>nd</sup> Paragraph:

Claims 31-55 were rejected under 35 U.S.C. § 112, 2<sup>nd</sup> Paragraph, as being indefinite.

Claims 32-52 and 54-55 were objected to for the recitation "preparation." The dependent claims are hereby amended to recite "compositions" as recited in claim 31.

Claims 43-44 were rejected over the recitation "glycoseaminoglycan" and "sodium hyaluronic acid." Claim 57 is hereby amended to refer to recitation "hyaluronic acid" to the recitation "glycoseaminoglycan" in claim 43. Claim 44 refers to claim 57.

Claims 46-48 are amended to recite "granules."

**Rejection Under 35 U.S.C. § 103(a):**

Claims 31-40, 43-50, 52, 53, and 55 were rejected under 35 U.S.C. § 103(a) as being unpatentable over NGK Spark Plug (JP 2198560) ("NGK") in view of Cassidy (6,280,474).

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*. All words in a claim must be considered in judging the patentability of that claim against the prior art. *In re Wilson*. (MPEP § 2143.03). When evaluating the scope of a claim, every limitation in the claim must be considered. See e.g. *In re Ochiai*. (MPEP § 2144.08). The evidentiary record fails to teach each limitation of the present invention. Specifically, the references taken as a whole or severally fail to teach a "moldable, injectable mass."

Claims 31 recited a "moldable mass." Claim 31 is hereby amended to further specify "moldable" as a "injectable" mass. The recitations "moldable" and "injectable" are supported by original disclosure variously at pages 9, 10, 14, and 16.

NGK relates to a rigid "sintered compact." (See page 17). A ceramic powder and other materials are mixed, "shaped to a predetermined shape," and then baked (sintered). (Page 8, second paragraph). Cassidy relates to a "dense, pre-formed hard tissue implant." (Column 3, lines 18-19). Each of NGK and Cassidy teaches away from an injectable implant. "Teaching away" is a per se demonstration of non-obviousness. (See *U.S. v Adams*, 383 US 39 (1966)).

Claims 41, 42, 51, and 54 were rejected under 35 U.S.C. § 103(a) as being unpatentable over NGK Spark Plug (JP 2198560) ("NGK") in view of Cassidy (6,280,474) and further in view of Larsson (5,196,201).

NGK and Cassidy teach away from the present invention. Larsson is not properly combinable with either NGK or Cassidy because the various liquid phases of Larsson are

incompatible with with a rigid sintered body of NGK or with a dense, pre-formed body of Cassidy.

**Conclusion:**

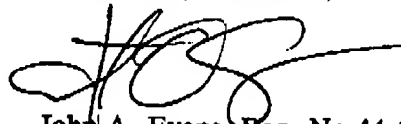
In view of the above, consideration and allowance are, therefore, respectfully solicited.

Accordingly, it is respectfully requested that the foregoing amendments be entered, that the application as so amended receive an examination on the merits, and that the claims as now presented receive an early allowance.

In the event the Examiner believes an interview might serve to advance the prosecution of this application in any way, the undersigned attorney is available at the telephone number noted below.

The Commissioner is hereby authorized to charge any fees or credit any overpayment associated with this communication, including any extension fees or fees for the net addition of claims, to Deposit Account No. 22-0185.

Respectfully submitted,



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